UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	Civil Action No. 3:10-CV-01723-JAP-TJB
Plaintiffs and Counterclaim-Defendants,	**FINAL PRETRIAL ORDER**
v.	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	
Defendants and Counterclaim-Plaintiffs.	

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16; and Hogan Lovells US LLP and McCarter & English, LLP having appeared for Plaintiffs[1], and Kelley, Drye, & Warren LLP having appeared for Defendants; the following Final Pretrial Order is hereby entered:

1. CASE SUMMARY

This is a patent infringement action under the Hatch-Waxman Act on four patents purportedly covering the Takeda Plaintiffs' Orally Disintegrating Tablet ("ODT") formulation of the anti-ulcer drug Prevacid®, which is marketed under the name Prevacid® SoluTab™. Plaintiffs are asserting U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent"), 7,875,292 ("the '292 patent") ('994, '942, and '292 patents, collectively, the "Takeda patents"), and 5,464,632 ("the '632 patent") against Defendants, who filed Abbreviated New Drug Application No. 200816 ("ANDA") with FDA, seeking to manufacture a generic version of Prevacid® SoluTab™ before expiration of the patents-in-suit and any extensions based on pediatric exclusivity.

[1] "Plaintiffs" refers to Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc. (collectively, "Takeda Plaintiffs"), and Ethypharm, S.A.

2. SUMMARY OF THE PARTIES' INFRINGEMENT POSITIONS

Plaintiffs contend that Defendants' ANDA product infringes the following claims:

- Claims 1 and 2 of the '994 patent;
- Claim 1 of the '942 patent;
- Claim 1 of the '292 patent; and
- Claims 1 and 4 of the '632 patent.

Defendants dispute that its ANDA product infringes the patents-in-suit and contend that its ANDA product does not meet the following claim limitations:

[redacted]

3. SUMMARY OF PARTIES' INVALIDITY POSITIONS

Defendants contend that the Takeda patents are invalid for the following reasons:

[redacted]

Defendants contend that the '632 patent is invalid for the following reasons:

[redacted]

Plaintiffs dispute that the Takeda patents are invalid and contend that the Takeda patents are not indefinite, are enabled and satisfy the written description requirement. Plaintiffs also dispute that the '632 patent is invalid and contend that the '632 patent is not anticipated, obvious, or indefinite. Thus, Plaintiffs contend the patents-in-suit are valid.

4. **PLAINTIFFS' WITNESSES**

Adam Zaeske

Adam Zaeske is the Vice President of managed markets and trade at Takeda Pharmaceuticals America, Inc. Takeda Pharmaceuticals America, Inc. is the U.S. based sales subsidiary of Takeda Pharmaceuticals North America, Inc., which recently changed its name to Takeda Pharmaceuticals U.S.A., Inc. Mr. Zaeske was the lead marketing person for the Prevacid® family as of mid-2008. Mr. Zaeske will testify to the commercial success of the Prevacid® SoluTab™ product, and the irreparable harm Plaintiffs would suffer if Plaintiffs were not granted an injunction against Defendants from infringing the patents-in-suit.

5. **DEFENDANTS' WITNESSES**

Srinivas Gurram

Mr. Gurram is the Senior Director, Regulatory Affairs of Zydus Pharmaceuticals USA Inc. Mr. Gurram has primary responsibility for interacting with the Federal Food and Drug Administration ("FDA") on Zydus's behalf, including as it relates to ANDAs generally, and, more specifically, the ANDA at issue in this case. If called, Mr. Gurram will testify concerning [redacted]

Dr. Brij Khera

Dr. Khera is Zydus's Executive Vice President and Chief Legal Officer. If called, Dr. Khera will testify about [redacted]

Zydus reserves the right to utilize deposition testimony for any proper purpose, including introducing additional testimony obtained during depositions conducted in this case and depositions conducted of Plaintiffs employees, agents and former agents in *Takeda Pharmaceutical Co. Ltd. v. Teva Pharmaceuticals USA Inc.*, 07CV331-SLR (D. Del). Pursuant

to the Court's directions, such deposition testimony will be provided to the Court, and will not be read directly into the record during trial.

6. PLAINTIFFS' EXPERT WITNESSES

Dr. M. Brian Fennerty

Dr. M. Brian Fennerty is a Professor of Medicine in the Department of Internal Medicine, Section of Gastroenterology at Oregon Health & Science. Dr. Fennerty is also a practicing physician and is Board permanently certified in internal medicine and in the subspecialty of gastroenterology. Dr. Fennerty will provide expert testimony regarding Takeda Plaintiffs' Prevacid® SoluTab™ product, including its unique status in the field, use of the product in patients for whom swallowing is an issue, as well as secondary considerations of nonobviousness of the patents-in-suit.

Dr. David E. Bugay

David E. Bugay, Ph.D., is an analytical and physical chemist with extensive experience analyzing and evaluating components of pharmaceutical products and various types of pharmaceutical formulations. Dr. Bugay also has extensive experience with analytical instruments including instruments used to obtain particle size measurements. As an expert in physical analytical characterization of pharmaceutical entities and analytical instruments, Dr. Bugay will testify that the drug product described in Defendants' ANDA infringes the Takeda patents and the '632 patent.

Dr. Stephen Byrn

Stephen Byrn, Ph.D., is the Charles B. Jordan Professor of Medicinal Chemistry at Purdue University. For over 40 years, Professor Byrn has taught courses in Pharmacy and authored two books and over 140 peer-reviewed publications in the field of pharmaceutical formulations. Professor Byrn also has extensive experience with particle size testing since 1980. As an expert in pharmaceutical formulations and particle size testing, Professor Byrn will offer expert testimony in rebuttal to Defendants' proffered evidence relating to invalidity of the '632 patent and the Takeda patents.

7. DEFENDANTS' EXPERT WITNESSES

Dr. Harry Brittain

Harry Brittain, Ph.D., is the Institute Director of the Center for Pharmaceutical Physics in Milford, New Jersey, where his research is focused in the fields of physical pharmacy, with special concentration on preformulation, formulation design, and substance characterization. Dr. Brittain is an expert in the areas of physical chemistry and physical pharmaceutics, formulation design, drug-excipient interactions, particle sizing, particle size distributions, and enteric-coated granules, as well as tablet and capsule formulations. Dr. Brittain has taught courses on, among other things, pharmaceutics and pharmaceutical science. Dr. Brittain has

authored more than 300 peer reviewed articles, more than 10 of which relate to particle size analysis. In accordance with his expertise, Dr. Brittain will testify consistently with the opinions set forth in his August 31, 2012 Expert Rebuttal Report and his February 12, 2013 Supplemental Expert Rebuttal Report.

Dr. Paula Meyer-Stout

Paula Meyer-Stout, Ph.D., is an Associate Professor of Pharmaceutics at West Virginia University ("WVU") School of Pharmacy, Morgantown, West Virginia, and a licensed pharmacist. Dr. Meyer-Stout is an expert in the areas particle sizing, particle size distributions, and enteric-coated granules, as well as tablet and capsule formulations in regard to their formulation components. In accordance with her expertise, Dr. Meyer-Stout will testify consistently with the opinions expressed in her January 17, 2012 Expert Report.

James Morrison

Mr. Morrison was employed by the FDA from 1965-2003 with increasing responsibilities during that nearly 40 year period. During his tenure with the FDA, Mr. Morrison worked on the enactment and implementation of the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act, including testifying at Congressional Hearings. In addition to his work with the FDA, Mr. Morrison has written extensively, including on issues related to the FDA's ANDA review process. Mr. Morrison is an expert in the area of FDA procedures and policy concerning drug regulatory issues and pharmaceutical manufacturers' compliance with FDA regulations and guidelines. In accordance with his expertise, Mr. Morrison will testify consistently with the opinions expressed in his February 12, 2013 Expert Rebuttal Report.

AMENDMENTS TO THIS PRETRIAL ORDER WILL NOT BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT IS DISALLOWED.

All In Limine Motions are pending.
Finds of Fact & Conclusions of Law to be Submitted by March 25, 2013

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Hon. Tonianne J. Bongiovanni, U.S.M.J.

DATED: March 8, 2013